TUCKER ELLIS LLP
MOLLIE F. BENEDICT SBN 187084
mollie.benedict@tuckerellis.com
MONEE TAKLA HANNA SBN 259468
monee.hanna@tuckerellis.com
515 S. Flower Street, 42nd Floor
Los Angeles, CA 90071
Telephone: 213.430.3400
Facsimile: 213.430.3409

TUCKER ELLIS LLP
DUSTIN B. RAWLIN (*pro hac vice*)
dustin.rawlin@tuckerellis.com
950 Main Avenue, Suite 1100
Cleveland, OH 44113-7213
Telephone: 216.592.5000
Facsimile: 216.592.5009

Attorneys for Defendant
MENTOR WORLDWIDE LLC

TUCKER ELLIS LLP
Chicago ◆ Cleveland ◆ Columbus ◆ Houston ◆ Los Angeles ◆ San Francisco ◆ St. Louis

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

ANITA LAUX,

Plaintiff,

v.

MENTOR WORLDWIDE, LLC; MENTOR CORPORATION; ETHICON, INC.; JOHNSON & JOHNSON and JOHN DOE DEFENDANTS # 1-10,

Defendants.

Case No. 2:16-cv-01026-ODW-AGR

Assigned to Honorable Otis D. Wright II

STATEMENT OF UNCONTROVERTED FACTS IN SUPPORT OF MENTOR WORLDWIDE LLC'S MOTION FOR SUMMARY JUDGMENT

Date: September 11, 2017
Time: 2:30 p.m.
Ctrm.: 5D

[Filed concurrently with Mentor's Motion for Summary Judgment and Memorandum in Support; Declaration of Dustin B. Rawlin; and [Proposed] Judgment]

Pursuant to Local Rule 56-1, Defendant Mentor Worldwide LLC hereby submits this Statement of Uncontroverted Facts.

All references to Exhibits contained herein are to the documents attached to, and authenticated by, the Declaration of Dustin B. Rawlin.

TUCKER ELLIS LLP
Chicago ♦ Cleveland ♦ Columbus ♦ Houston ♦ Los Angeles ♦ San Francisco ♦ St. Louis

UNCONTROVERTED FACTS IN SUPPORT OF SUMMARY JUDGMENT

Moving Party's Uncontroverted Facts:	Supporting Evidence:
1. Plaintiff has brought suit against Mentor Worldwide LLC claiming that she has suffered certain injuries as a result of manufacturing defects, negligence, and breach of warranty from her Mentor Saline Breast Implants.	Compl. ¶¶ 32-56, attached as **Exhibit A** to the Declaration of Dustin B. Rawlin ("Rawlin Decl.").
2. Plaintiff asserts that the Mentor Saline Breast Implants "contained manufacturing defects when they left the Defendants' possession."	Compl. ¶ 46.
3. Plaintiff alleges that Mentor violated vague and generic Current Good Manufacturing Practices. She alleges the implants "were not manufactured in accordance with the FDA's Quality System Regulations and Current Good Manufacturing Practices, 21 C.F.R. § 820.1, *et seq*."	Compl. ¶¶ 14(b), 46(l).
4. Plaintiff alleges Mentor was "grossly negligent" because the Mentor Saline Breast Implants contained manufacturing defects.	Compl. ¶ 49.
5. Plaintiff alleges that she has suffered "debilitating bio-toxin disease, auto-immune disorders, respiratory, neurological, and immune diseases, fibromyalgia, fibrotic masses and fibrils (the start of silicosis, as silica from breast implants was flaking into the wall of Plaintiff's chest), pain in the forearms and hands, pain in the right side of the body near the liver, difficulty breathing, pain in the middle of the chest, a cracking sound on the right side of the neck, vision and eye issues, severe vertigo, tinnitus, pain, sever fatigue and disfigurement."	Compl. ¶ 37.
6. On November 12, 1999, Mentor submitted a Premarket Approval ("PMA") application for its Saline Breast Implants.	PMA Approval Order and Summary of Safety and Effectiveness for P990075, attached as **Exhibit B** to Rawlin Decl.

7. Plaintiff's expert, Dr. Pierre Blais, testified before an FDA panel regarding his concerns with Mentor Saline Breast Implant valves. He testified that the diaphragm valves of Mentor Saline Breast Implants were defective. Dr. Blais attempted to publish his research and theories regarding defective valves, but the publisher told him it was "a resolved issue, and there was no interest in it and therefore, it was not topical."	Deposition of Pierre Blais ("Blais Dep.") at 161:15-164:21, 167:2-11, relevant excerpts attached as **Exhibit C** to Rawlin Decl.
8. On May 10, 2000, the FDA found that the Mentor Saline Breast Implants as designed, manufactured and labeled are safe and effective. The FDA issued an Approval Order. The approvals remain in effect and have never been suspended or revoked.	PMA Approval Order and Summary of Safety and Effectiveness for P990075, attached as **Exhibit B** to Rawlin Decl. Federal Register/Vol. 66, No. 130, July 6, 2001 Notices, TABLE 1: List of Safety and Effectiveness Summaries for Approved PMAs Made Available from January 1, 2001 to March 31, 2001. Declaration of Hoshang Kotivand, ¶ 4 ("Kotivand Decl."), attached as **Exhibit D** to Rawlin Decl.
9. Mentor Saline Breast Implants can only be sold to healthcare professionals in accordance with the design, manufacturing and labeling specifications approved by the FDA.	PMA Approval Order and Summary of Safety and Effectiveness for P990075.
10. Mentor's shipping department received and shipped only those implants that originated from the Finished Goods Inventory.	Kotivand Decl. ¶ 6.

TUCKER ELLIS LLP
Chicago ♦ Cleveland ♦ Columbus ♦ Houston ♦ Los Angeles ♦ San Francisco ♦ St. Louis

11. No finished medical devices entered Finished Goods Inventory without being approved by Mentor's Quality Assurance department, which approved implants for distribution. Finished Goods Inventory operated under a first-in, first-out system of inventory.	Kotivand Decl. ¶ 7.
12. Mentor packaged the breast implants at issue with materials that are commonly used in the implant industry. The breast implants were placed in inner and outer thermoform trays. These thermoform trays were made from polyethylene terephthalate (PET-G), a very durable substance. The design of the inner thermoform tray was contoured to fit the shape of the implants to prevent the breast implants from shifting. The inner thermoform also serves as a convenient sterile container in which the physician can perform the intra-operative leak test of the device as described in the Product Insert Data Sheet. The outer thermoform tray was designed to serve as a second layer of protection for the device as well as to provide a dual sterile barrier. Mentor then sealed the implants in the inner and outer thermoform trays with Tyvek lids.	Kotivand Decl. ¶ 8.
13. Mentor's quality assurance inspection and testing, which takes place before the implants are released to Finished Goods, would have located a defect in the valves or the shell. Mentor does not distribute, and would not have distributed, breast implants that have failed quality assurance testing or otherwise contained a defect. Based upon this testing, the implant at issue in this case contained no defects.	Kotivand Decl. ¶ 9.
14. As a part of normal quality control procedures, the 200555-001 valve plugs ordered from the manufacturer, Porges, were received by Mentor on December 23, 2004 for lot 5610526 and June 1, 2005 for lot 5640757. They were accompanied by a Certificate of Conformance specific to this order. Per procedure, the order was quarantined while incoming inspection to drawing number 200555 per QCIC 200555 and review of the Certificate of Conformance were completed. They were released to manufacturing inventory on January 1, 2005 for lot 5610526 and June 21, 2005 for lot 5640757.	Kotivand Decl. ¶ 10.

TUCKER ELLIS LLP
Chicago ♦ Cleveland ♦ Columbus ♦ Houston ♦ Los Angeles ♦ San Francisco ♦ St. Louis

15. The order consisting of 200556-001 Diaphragm Valves Med 4515 were received by Mentor on March 28, 2005 for lot 5610526 and June 14, 2005 for lot 5640757 from the manufacturer Innovative Surgical Products. These components also were accompanied by a Certificate of Conformance, and were quarantined until the completion of incoming inspection to drawing number 200556 per QCIC 200556 and review of the Certificate of Conformance were completed. The valves passed all incoming inspection criteria and were released to manufacturing inventory on April 1, 2005 for lot 5610526 and June 21, 2005 for lot 5640757.	Kotivand Decl. ¶ 11.
16. During the assembly processes which affix all of the component parts, including shells, patches, washers, and the volume marking tab into the finished implant, Catalog No. 350-3250, Lot No. 5610526 and Catalog No. 350-3250, Lot. No. 5640757, 100% inspections were conducted at the completion of each process. Specifically, at the conclusion of the vulcanization of the diaphragm valve assembly onto the shell, all devices comprising lot numbers 5601526 and 5640757 were 100% inspected per QCIC 000128, drawing 600987. Four (4) device(s) were rejected and scrapped from lot 5601526 based on this inspection. One (1) device(s) was rejected and scrapped from lot 5640757 based on this inspection. Immediately prior to packaging, the devices were again 100% inspected, filled with the nominal fill volume of air and 100% leak tested by submersion in isopropyl alcohol per QCIC 000171. This leak test ensures both shell and valve integrity and functionality.	Kotivand Decl. ¶ 12.
17. On June 3, 2005, the 148 devices in lot number 5601526 were sterilized via dry heat per PROC 000304 with appropriate biological indicators. On June 10, 2005, sterility verification was obtained from microbiology for this lot. On June 7, 2005, the 146 devices comprising Finished Goods lot number 5601526 were released to distribution inventory.	Kotivand Decl. ¶ 13.

TUCKER ELLIS LLP
Chicago ♦ Cleveland ♦ Columbus ♦ Houston ♦ Los Angeles ♦ San Francisco ♦ St. Louis

18. On October 23, 2005, the 151 devices in lot number 5640757 were sterilized via dry heat per PROC 000304 with appropriate biological indicators. On November 1, 2005, sterility verification was obtained from microbiology for this lot. On October 26, 2005, the 151 devices comprising Finished Goods lot number 5640757 were released to distribution inventory.	Kotivand Decl. at ¶ 14.
19. Based upon the numerous in-process procedures, inspections and testing, all accomplished using calibrated and/or validated procedures and equipment approved by the FDA, the implant(s) at issue in the case were sterile and contained no defects or mold at the time they left Mentor's control.	Kotivand Decl. at ¶ 15.
20. From 1998 through 2005, and continuing through today, all design, raw-materials, manufacturing, and in-process testing procedures and protocols utilized in the manufacturing, storage and distribution of Mentor breast implants, including the Plaintiff's, are and were subject to annual FDA review and on-site inspection, as well as inspection by a third-party independent quality consultant. During all of these inspections, Mentor was found to be in compliance with all sections of the CGMP, QSR, 21 CFR Part 820, a federally mandated quality system regulation also known as Current Good Manufacturing Practice, Final Rule.	Kotivand Decl. at ¶ 16.
21. The implants at-issue conformed to Mentor's design and manufacturing specifications as well as all applicable FDA requirements and had no defects at the time they left Mentor's control.	Kotivand Decl. at ¶ 17.
22. Dr. Bunkis performed breast augmentation surgery on Plaintiff on December 30, 2005 and placed two Mentor 250cc High Profile Smooth Saline breast implants, filled to 250cc. There were no complications during the procedure.	Deposition of Dr. Juris Bunkis ("Bunkis Dep.") at 70:20-74:7, relevant excerpts attached as **Exhibit E** to the Rawlin Decl.
23. Prior to placing the Mentor implants into Plaintiff, Dr. Bunkis examined them to make sure that they were sterile and free from defects. The implants were soaked in an antibiotic solution for 20-30 minutes. He also leak-tested them and found no anomalies.	Bunkis Dep. at 74:11-76:3.

TUCKER ELLIS LLP
Chicago ♦ Cleveland ♦ Columbus ♦ Houston ♦ Los Angeles ♦ San Francisco ♦ St. Louis

24. Dr. Bunkis saw Plaintiff post-operatively at least two times and Plaintiff was happy, had no complications, and reported no complaints.	Bunkis Dep. at 78:4-6, 80:6-11, 80:24-81:7, 81:19-82:2.
25. On May 23, 2014, Dr. Susan Kolb explanted the Mentor saline breast implants from Plaintiff.	Deposition of Dr. Susan Kolb ("Kolb Dep.") at 57:9-11, relevant excerpts attached as **Exhibit F** to the Rawlin Decl.
26. The implants were intact when removed from Plaintiff.	Kolb Dep. at 143:19-22.
27. Dr. Kolb sent the capsules from the implants to pathology.	Kolb Dep. at 82:10-13.
28. Cultures of Plaintiff's breast tissue were negative.	Kolb Dep. at 59:10-11, 74:6-7, 80:5-7. 81:3-22.
29. Pathology reports of Plaintiff's breast tissue were normal.	Kolb Dep. at 82:10-17.
30. Dr. Kolb did not test the contents of the implant for mold.	Kolb Dep. at 16:19-21, 83:13-18.
31. Dr. Kolb does not know what kind of mold was purportedly in Plaintiff's body or implants.	Kolb Dep. at 53:9-11, 123:11-12.
32. Dr. Kolb does not know if the mold purportedly in Plaintiff's body or implants produced biotoxins.	Kolb Dep. at 53:12-54:13.
33. Dr. Kolb has performed no scientific or medical testing to determine how much, if any, mold there was in Plaintiff's body or implants.	Kolb Dep. at 16:19-21, 53:25-54:13, 83:13-18.
34. Dr. Kolb did not test the saline or contents of the implant.	Kolb Dep. at 16:16-21, 82:24-83:7, 122:10-22.
35. Dr. Kolb does not what the debris inside Plaintiff's implant was.	Kolb Dep. at 32:1-11.
36. Dr. Kolb cannot identify what was inside the saline of the implant without testing it or looking at it under a microscope.	Kolb Dep. at 83:13-18, 122:7-9, 139:20-22.
37. Dr. Kolb did not observe saline leaking from the implants.	Kolb Dep. at 75:21-23.
38. Dr. Kolb did not see mold or bacteria inside the implant, and her operative report does not note the presence of mold.	Kolb Dep. at 77:7-22.

TUCKER ELLIS LLP
Chicago ♦ Cleveland ♦ Columbus ♦ Houston ♦ Los Angeles ♦ San Francisco ♦ St. Louis

39. Dr. Kolb did not measure the amount of saline allegedly missing from the implants.	Kolb Dep. at 142:23-143:18.
40. Dr. Kolb did not have a medical mycologist investigate what was inside Plaintiff's implants.	Kolb Dep. at 96:22-97:2.
41. Dr. Kolb knows there is mold within the implants because Dr. Blais looks at it under the microscope, or the mold "grows out" within several weeks.	Kolb Dep. at 29:2-7.
42. Dr. Kolb identifies defects in the Mentor saline implant valves by looking at the valves when she removes the implants.	Kolb Dep. at 28:13-18.
43. Dr. Kolb admits that implants can become contaminated without being defective.	Kolb Dep. at 25:14-22.
44. Dr. Kolb admits that it is important to know what kind of mold is inside an implant because particular molds may not be toxic.	Kolb Dep. at 52:1-53:21.
45. Dr. Kolb does not know whether all molds are toxic, or which molds are toxic.	Kolb Dep. at 53:1-8.
46. Dr. Kolb knows the mold allegedly inside of Plaintiff's implants was toxic because Plaintiff had biotoxin disease.	Kolb Dep. at 53:12-21.
47. Dr. Blais believes Plaintiff has "degraded silica in proximity to the degraded zone in her implants," which would have been found in the capsule around the implant.	Blais Dep. at 64:9-14, 67:9-11.
48. Dr. Blais did not perform any tests on Plaintiff's implant capsules.	Blais Dep. at 20:20-21:3.
49. Dr. Blais did not perform any tests for degraded silica on Plaintiff's breast tissue.	Blais Dep. at 21:4-6, 64:15-19.
50. Dr. Blais is unaware of any test that can confirm whether silicone breast implant shells can degrade and release silica into the breast tissue.	Blais Dep. at 66:12-16.
51. Nobody has tested Plaintiff's breast tissue or capsules for degraded silica.	Blais Dep. at 64:20-24, 66:17-20, 69:9-20
52. There is no toxicology or pathology results supporting Dr. Blais' theory that Plaintiff suffered from degraded silica.	Blais Dep. at 67:14-20.
53. Dr. Blais did not perform any tests or studies on the saline solution of Plaintiff's implant.	Blais Dep. at 21:10-14.
54. Dr. Blais did not perform any tests or studies on the debris inside Plaintiff's implant.	Blais Dep. at 21:10-14.
55. When Dr. Blais received the implants, neither implant was perforated or ruptured.	Blais Dep. at 53:6-9.

TUCKER ELLIS LLP
Chicago ♦ Cleveland ♦ Columbus ♦ Houston ♦ Los Angeles ♦ San Francisco ♦ St. Louis

56. Dr. Blais did not see saline leaking from either of Plaintiff's implants. He did not see visible streams of fluid coming from the valve.	Blais Dep. at 55:22-56:1.
57. The implants contained the same amount of saline as they did when initially implanted.	Blais Dep. at 171:21-25.
58. Dr. Blais cannot provide information identifying how the Mentor Saline Breast Implant deviated from manufacturing specifications.	Blais Dep. at 74:9-75:7.
59. Dr. Blais did not have any materials available concerning the design specifications of the valves when he studied Plaintiff's implants and valves.	Blais Dep. at 184:7-11.
60. Dr. Blais did not test the valves or measure against the valves against their actual specifications. He "interpolate[d] information [he] had about valve standards and how such valves could be characterized in a quality assurance program."	Blais Dep. at 115:14-24, 184:19-185:7.
61. Dr. Blais did not compare the implants to their lot histories to confirm measurements and consistency with PMA specifications.	Blais Dep. 182:13-183:7.
62. Dr. Blais has never tested his theory that Mentor valves allow fluid to flow back into the breast implant causing "auto inflation."	Blais Dep. at 137:24-138:5, 140:2-17.
63. Dr. Blais has never published his theory of auto inflation theory.	Blais Dep. at 166:21-167:1.
64. Dr. Blais testifies that the Mentor diaphragm valve is defectively designed.	Blais Dep. at 163:4-6.
65. Dr. Blais testifies that all of the Mentor valves have the same problems because they all manufactured in the same place.	Blais Dep. at 163:8-12.
66. Dr. Blais testified that if the implants incorporate "the second generation diaphragm valve," then they are defectively designed.	Blais Dep. at 179:20-180:2.
67. Dr. Blais admits that there are other mechanisms (besides manufacturing defects) by which an implant may become contaminated.	Blais Dep. at 144:3-14.

TUCKER ELLIS LLP
Chicago ♦ Cleveland ♦ Columbus ♦ Houston ♦ Los Angeles ♦ San Francisco ♦ St. Louis

68. Dr. Blais has issued substantially similar reports detailing manufacturing defects with the Mentor valves utilized by three other plaintiffs. All three plaintiffs lost on summary judgment.	Blais Report Prepared for JoAnn Cottengim, No. 2:2005cv00161 (E.D. Ky.), attached as **Exhibit G** to Rawlin Decl.; Blais Report Prepared for Deborah Alfred, No. 05-483-C (W.D. Ky.), attached as **Exhibit H** to Rawlin Decl.; Blais Report prepared for Elizabeth Lakey, No.1:05-cv-00929 (N.D. Ga.) attached as **Exhibit I** to Rawlin Decl.
69. Dr. Blais believes that Mentor's sterilization protocols are sufficient to prevent contamination.	Blais Dep. at 144:15-24.
70. Dr. Blais believes that the sterilization and manufacturing practices of Mentor Worldwide LLC appear to be adequate to prevent contamination of the saline filling.	Blais Dep. at 145:25-146:10.
71. Dr. Blais did not follow his own standard protocol for determining whether Mentor valves are defective in preparing his report in this case.	Blais Dep. at 149:5-11.
72. Dr. Blais does not know whether there was sufficient amount of biotoxins in Plaintiff's implant to cause illness.	Blais Dep. at 95:4-24.
73. Dr. Blais did not test the saline inside the implant.	Blais Dep. at 81:17-82:7.
74. Dr. Blais did not perform any tests to determine whether the contents of the implant were mold.	Blais Dep. at 129:10-130:17.
75. Dr. Blais does not know how much bacteria, or what kind of bacteria, was inside Plaintiff's implant.	Blais Dep. at 209:4-12.
76. Dr. Blais does not know how much mold, if any, is inside the implant.	Blais Dep. at 95:3-14.
77. Dr. Blais does not know if mold has ever been found in Plaintiff's body.	Blais Dep. at 137:9-17.

TUCKER ELLIS LLP
Chicago ♦ Cleveland ♦ Columbus ♦ Houston ♦ Los Angeles ♦ San Francisco ♦ St. Louis

78. Dr. Blais did not perform any acid-fast cultures of Plaintiff's tissues.	Blais Dep. at 161:4-9.
79. Dr. Blais did not perform any differential stains on Plaintiff's tissues.	Blais Dep. at 161:10-12.
80. Dr. Blais did not perform any gram staining on Plaintiff's tissues.	Blais Dep. at 161:13-14.
81. Dr. Blais is not providing testimony on causation.	Blais Dep. at 171:12-20.
82. Mentor provides a Product Replacement Policy and Standard Advantage Limited Warranty ("Limited Warranty") for Smooth Round High Profile Saline breast implants.	Declaration of Nicole Bwrede, ¶ 2 ("Brewde Decl."), attached as **Exhibit J** to the Rawlin Decl.
83. Under the Limited warranty, to be reimbursed for out of pocket costs related to a qualified revision surgery, a patient must (1) make a request for financial assistance to Mentor Customer Quality; (2) have her surgeon contact Mentor to confirm the eligible event; (3) sign a release; and (4) submit information to Mentor so that Mentor can evaluate the claim.	Bwrede Decl. at ¶ 3.
84. The patient must submit the following information: the patient's file and operative report of the initial surgery with identification (serial numbers) of the Mentor implants placed; the operative report for the revision surgery; copies of the bills showing operating room and/or anesthesia and surgical fee expenses incurred for the revision surgery; copies of forms showing any relevant insurance reimbursements; authorization, signed by the patient, allowing return of the explanted implant to Mentor; and the removed and decontaminated implant within 60 days of explantation.	Bwrede Decl. at ¶ 3.
85. Plaintiff contacted Mentor Customer Quality on February 23, 2015 and June 17, 2015 to make a claim regarding the same event. She did not provide any information regarding the serial number of her implants.	Bwrede Decl. at ¶ 4.
86. Plaintiff did not provide any information regarding the serial number of her implants to the Mentor Customer Quality representative.	Bwrede Decl. at ¶ 4.

TUCKER ELLIS LLP
Chicago ♦ Cleveland ♦ Columbus ♦ Houston ♦ Los Angeles ♦ San Francisco ♦ St. Louis

87. Plaintiff's surgeon never contacted Mentor Customer Quality to confirm the occurrence of an eligible event.	Bwrede Decl. at ¶ 4.
88. Plaintiff has not signed a release and has not returned her explanted devices to Mentor's Product Evaluation Department.	Bwrede Decl. at ¶ 4.
89. Plaintiff's former counsel, Mr. Alan C. Milstein, admitted he could not oppose summary judgment motion.	Declaration of Alan C. Milstein in Support of *Ex Parte* Application to Withdraw as Counsel for Plaintiff Anita Laux and Motion to Stay All Deadlines for 30 Days, ECF No. 44-2, ¶ 18, attached as **Exhibit K** to the Rawlin Decl.

DATED: August 4, 2017

TUCKER ELLIS LLP

By: */s/ Monee Takla Hanna*
Dustin B. Rawlin
Mollie F. Benedict
Monee Takla Hanna
Attorneys for Defendant
MENTOR WORLDWIDE LLC

TUCKER ELLIS LLP
Chicago ♦ Cleveland ♦ Columbus ♦ Houston ♦ Los Angeles ♦ San Francisco ♦ St. Louis